

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

MDL No. 2419
Master Docket:
1:13-md-2419-RWZ

This Document Relates To:

Tallman, 1:13-cv-10349; *Landon*, 1:13-cv-10352; *Shrock*, 1:13-cv-10353; *Rethlake*, 1:13-cv-10354; *Oblinger*, 1:13-cv-10355; *Wyres*, 1:13-cv-10356; *Geisler*, 1:13-cv-10357; *Ginther*, 1:13-cv-10363; *Klemm*, 1:13-cv-10371; *Pavlekovich*, 1:13-cv-10373; *Copsey*, 1:13-cv-10503; *Tolbert*, 1:13-cv-10507; *Huff*, 1:13-cv-10511; *Craig*, 1:14-cv-12367; *Bostic*, 1:14-cv-12371; *Smith*, 1:14-cv-12531; *Lenhart*, 1:14-cv-12561; *Polk*, 1:14-cv-12573; *Pringle*, 1:14-cv-12574; *Elliott*, 1:14-cv-12597; *Alcozar*, 1:14-cv-12598; *Durben*, 1:14-cv-12599; *Frick*, 1:14-cv-12611; *Holden*, 1:14-cv-12616; *Wegner*, 1:14-cv-12619; *Wolfe*, 1:14-cv-12622; *Glon-Ullery*, 1:14-cv-12838; *Barnes*, 1:14-cv-12864; *Briggs*, 1:14-cv-12869; *Browning*, 1:14-cv-12872; *Hunt*, 1:14-cv-12875; *Lay*, 1:14-cv-12909; *Haas*, 1:14-cv-12912; *Konanz*, 1:14-cv-12913; *McClure*, 1:14-cv-12914; *Owen*, 1:14-cv-13006; *Pinnyci*, 1:14-cv-13010; *Robinson*, 1:14-cv-13011; *Pedler*, 1:14-cv-13012; *Probst*, 1:14-cv-13014; *Shafer*, 1:14-cv-13015; *Pletcher*, 1:14-cv-13016; *Soli*, 1:14-cv-13017; *Koziatek*, 1:14-cv-13018; *Jones*, 1:14-cv-13021; *McQueen*, 1:14-cv-13025; *Cookson*, 1:14-cv-13081; *Allen*, 1:14-cv-13082; *Garl*, 1:14-cv-13083; *Copp*, 1:14-cv-13084; *Pritchard*, 1:14-cv-13157; *Lawson*, 1:14-cv-13158; *Cobb*, 1:14-cv-13200; *Greenwood*, 1:14-cv-13202; *Grice*, 1:14-cv-13204; *Holt*, 1:14-cv-13206; *Hurst*, 1:14-cv-13207; *Ivory*, 1:14-cv-13209; *Sims*, 1:14-cv-13212; *Sinn*, 1:14-cv-13213; *Stokes*, 1:14-cv-13217; *VanSchoiack*, 1:14-cv-13218; *Dillon*, 1:14-cv-13220; *Rice*, 1:14-cv-13257; *Lock*, 1:14-cv-13262; *Reed*, 1:14-cv-13265; *Wilfing*, 1:14-cv-13267; *Yoe*, 1:14-cv-13268; *Vitou*, 1:14-cv-13294; *Tirotta*, 1:14-cv-13296; *Smith*, 1:14-cv-13304; *Robinson*, 1:14-cv-13307; *Kaser*, 1:14-cv-13322; *Hinkle*, 1:14-cv-13323; *Miller*, 1:14-cv-13324; *Kubiszewski*, 1:14-cv-13325; *Jackson*, 1:14-cv-13327; *Roark*, 1:14-cv-13329; *Romano*, 1:14-cv-13332; *Walter*, 1:14-cv-13335; *Rulli*, 1:14-cv-13411; *Behrens*, 1:14-cv-13412; *Tuff*, 1:14-cv-13413; *Frain*, 1:14-cv-13414; *Fortier*, 1:14-cv-13415; *Mohr*, 1:14-cv-13483; *Sieczko*, 1:14-cv-13484; *Surowiec*, 1:14-cv-13486; *Troxel*, 1:14-cv-13488; *Trost*, 1:14-cv-13489; *Redman*, 1:14-cv-13493; *Ross*, 1:14-cv-13494; *Reinhardt*, 1:14-cv-13495; *Jackson*, 1:14-cv-13661; *Pinkstaff*, 1:14-cv-13719; and *Calvo-Nelson*, 1:14-cv-13734.

REDACTED

**DEFENDANT LIBERTY INDUSTRIES, INC.'S MEMORANDUM OF LAW IN
SUPPORT OF ITS OMNIBUS MOTION FOR SUMMARY JUDGMENT IN
CASES FILED BY PLAINTIFFS INJECTED IN INDIANA**

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OVERVIEW

Summary judgment must enter for Liberty Industries, Inc. (“Liberty”) because there is no evidence to support any Plaintiffs’ claims against Liberty.¹ Plaintiffs filed Short Form Complaints against Liberty between Dec. 19, 2013 and Sept. 30, 2014 in which they all adopt certain allegations of the Master Complaint.² All of the Short Form Complaints identify Plaintiffs’ claims as negligence and gross negligence (Count I) and punitive damages (Count XIV). These claims fail as a matter of law because Liberty did not breach any duty to any Plaintiffs and did not cause Plaintiffs’ injuries. Liberty also did not engage in any conduct warranting a finding of gross negligence or imposing punitive damages. In those matters in which Plaintiffs also allege loss of consortium (Count XIII), those claims similarly fail because of the shortcomings of the negligence claims. The “wrongful death punitive damages” claims (Count XII) fail not only for the same reasons as the negligence and punitive damages claims – lack of causation and lack of conduct warranting such damages – but also because such damages are not recoverable in Indiana. Any potential claim based on an alleged violation of M.G.L. c.93A is likewise fatally flawed (Count V). Therefore, judgment must enter for Liberty on all claims brought by all Indiana Plaintiffs.

¹ There are currently 98 cases pending against Liberty in which the Plaintiffs were allegedly injected with MPA in Indiana (“Indiana Plaintiffs”). All but one of these matters are the subject of Liberty Industries, Inc.’s Omnibus Motion for Summary Judgment on All Cases Filed by Plaintiffs Injured in Indiana (“Omnibus Motion”). See **Appendix I**, containing a list of those cases to which this Omnibus Motion pertains, together with a summary of information extracted from the complaints filed by the Indiana Plaintiffs. Appendix I also identifies those matters in which Plaintiffs assert a claim for “wrongful death punitive damages” and loss of consortium. The only Indiana case not subject to this Omnibus Motion is *Lambert*, Case No. 1:13-cv-10351, as a summary judgment motion was filed in that matter on Sept. 11, 2014.

² One case filed by Indiana Plaintiffs is not a Short Form Complaint, but rather is a full-length complaint. See *Pinkstaff*, Case No. 1:14-cv-13719. However, the “negligence and gross negligence” claim asserted against Liberty (Count VI), (and the loss of consortium (Count VIII) and punitive damages (Count IX) claims) parrot the allegations of the Master Complaint. Compare, e.g. Case No. 1:14-cv-13719, Dkt. No. 1 at ¶¶ 152-162, and 1:13-md-2419 at Dkt. No. 545 at ¶¶ 125-135.

ARGUMENT

I. The Summary Judgment Standard's Shifting Burdens of Proof

Summary judgment shall be granted to a moving party when it shows that “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). A party may show that a fact cannot be genuinely disputed by either citing to material in the record, or showing that “an adverse party cannot produce admissible evidence to support the fact.” *Id.* at 56(c)(1). Summary judgment must enter against a non-moving party that bears the burden of proof at trial, but cannot prove an essential element of her case. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *see also Whetstine v. Gates Rubber Co.*, 895 F.2d 388, 391-392 (7th Cir. 1990) (moving party has initial burden of proof to show no genuine issue of material fact). Summary judgment must enter:

against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be ‘no genuine issue as to any material fact,’ since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts material. The moving party is ‘entitled to a judgment as a matter of law’ because the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof.

Celotex, 477 U.S. at 322-323 (internal citations omitted). A function of Rule 56 is to eliminate claims or defenses that are factually unsupported. The Rule should be interpreted in a manner consistent with this purpose. *See id.* at 323-324. The moving party meets its burden of proof by demonstrating an “absence of evidence to support the nonmoving party's case.” *Id.* at 326.

Once the moving party has met its burden, the burden then shifts to the nonmoving party. Judgment shall enter for the moving party, “unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 424, 250 (1986); *see also Whetstine*, 895 F.2d at 392. If the evidence is only

“colorable” or is “not significantly probative, [] then summary judgment may be awarded.”

Anderson, 477 U.S. at 249-250 (internal citations omitted). The judge’s inquiry is to determine whether there is any need for trial. *See id.* at 250. The inquiry is whether:

a fair-minded jury could return a verdict for the plaintiff on the evidence presented. The mere existence of a scintilla of evidence in support of the plaintiff’s position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff. The judge’s inquiry, therefore, unavoidably asks whether jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict [].

Id. at 252. The nonmoving party has the “responsibility of going beyond the pleading and setting forth specific facts” that will be “outcome determinative under the governing law.” *Whetstine*, 895 F.2d at 392.

II. Applicable State Law

A court presiding over multi-district litigation (“MDL”) must apply the choice of law rules of the transferor court. *See, e.g., In re Volkswagen and Audi Warranty Extension Litig.*, 692 F.3d 4, 18-19 (1st Cir. 2012). These matters were commenced in state or federal court in Indiana and transferred into the MDL, or were filed directly in the MDL. *See* Appendix I. The Plaintiffs all allege they were injected with methylprednisolone acetate (“MPA”) compounded by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center (“NECC”) at clinics in Indiana. *See id.*

Indiana applies a rebuttable presumption or rule of *lex loci*. *See Simon v. U.S.*, 805 N.E.2d 798, 804-805 (Ind. 2004). When plaintiff’s domicile and place of injury are the same, there is no reason to disregard the presumption. *See Alli v. Eli Lilly & Co.*, 854 N.E.2d 372, 379 (Ind. Ct. App. 2006). Some Plaintiffs chose to file directly in the MDL in Massachusetts. Massachusetts utilizes the “functional” approach. *See e.g. Lou v. Otis Elevator Co.*, 933 N.E.2d 140, 150 (Mass. App. Ct. 2010) (“Massachusetts generally follows a functional approach to

resolving choice of law questions on substantive matters, eschewing reliance on any particular choice of law doctrine... Though we do not tie our analysis to any single doctrine, examination of our cases reveals that we often find useful guidance in the Restatement (Second) of Conflict of Laws.”). The Restatement states that the applicable law is that of the place where the injury occurred unless “some other state has a more significant relationship [.]” Restatement (Second) of Conflict of Laws § 146 (1971).

In short, all Plaintiffs were injured in Indiana, and most Plaintiffs live in Indiana. *See* Appendix I. There is no evidence to demonstrate that any other state has a more significant relationship to the injury than the place where the injury occurred. Therefore, Indiana law applies. *See Simon*, 805 N.E. 2d at 804-805, and *Alli*, 854 N.E.2d at 379; *Otis Elevator Co.*, 933 N.E.2d at 150; Restatement (Second) of Conflict of Laws § 146. Plaintiffs cannot prove essential elements of their state law claims such that summary judgment should enter for Liberty.

III. Statement of Undisputed Material Facts

A. Introduction.

Liberty built three cleanrooms for NECC and/or Ameridose in 2005, 2006, and 2008 (collectively “Cleanrooms”). *See* Affidavit of Jeffrey Erickson (“Erickson Aff.”), attached hereto as **Exhibit A**, at ¶ 1. The 2005 and 2006 Cleanrooms were constructed for NECC, and the 2008 Cleanroom was constructed for Ameridose. *See id.* NECC compounded contaminated MPA at its Facility. *See* Master Complaint at Exhibits 1 – 5 (state and federal reports). Although Plaintiffs do not know in which Cleanroom the contaminated MPA was compounded, MPA ingredients were found in the 2006 Cleanroom during an inspection of the Facility in July, 2014. *See* Erickson Aff. at ¶¶ 13-14; *see also* Master Complaint at ¶ 133. Liberty has not

received any indication that the contaminated MPA was compounded in the 2005 or 2008 Cleanrooms. *See* Erickson Aff. at ¶ 13.

B. The 2006 Cleanroom Contract Required an ISO Class 6 Cleanroom in Compliance with ISO Standard 14644-1.

In November, 2005, Liberty offered to NECC to provide a cleanroom which would comply with the requirements of ISO Standard 14644-1 and NECC's required technical specifications. *See* November 21, 2005 quote from Liberty to NECC, attached to the Erickson Aff. as **Exhibit 1**. NECC accepted Liberty's quote on November 28, 2005. *See* Nov. 28, 2005 acceptance from NECC to Liberty, attached to the Erickson Aff. as **Exhibit 2**.

"ISO Standard 14644-1" refers to a standard developed by the International Organization for Standardization ("ISO"), a worldwide federation of national standards bodies, that applies to cleanrooms and related controlled environments. *See* Erickson Aff. at ¶ 7. ISO 14644 is comprised of several parts that pertain to particular aspects of cleanrooms. *See id.* ISO 14644-1 provides the standard for classifying air cleanliness in cleanrooms. *See id.* The class designations indicate the amount and size of air particles that are permitted to enter a room, and the amount of pressure the room must maintain. *See id.* The lower the classification, the fewer particles permitted, and the "cleaner" the room. *See id.* It was this standard, ISO 14644-1, that Liberty contracted to comply with when it constructed the 2006 Cleanroom. *See* Erickson Aff. at Exhibits 1 and 2.

The 2006 Cleanroom was constructed as an ISO Class 6/7/8 Cleanroom. *See id.* and Erickson Aff. at ¶ 7. The suite of rooms consisted of a main room of ISO Class 6, with anterooms that were ISO Classes 7 and 8. *See id.* The main room of the 2006 Cleanroom is the lowest class (ISO Class 6), and by definition "cleaner" than the smaller preparation or freight rooms adjacent to it (ISO Classes 7 and 8). *See id.* The main room was to function under

positive pressure such that the air would flow from the lowest class room out to the higher class room. *See id.* at ¶ 7. Thus, in the 2006 Cleanroom, the positive pressures were higher in the main room. *See id.* If a door were opened, air would flow from the Class 6 main room to the preparation room (Class 7) and then to the freight room (Class 8). *See id.*

Although the parties communicated to coordinate the construction of the 2006 Cleanroom, Liberty's obligation to provide an ISO Class 6 Cleanroom in compliance with ISO 14644-1 did not change. *See* Erickson Aff. at Exhibits 1 and 2. Liberty's work in the construction of the Cleanroom included construction of the walls and ceilings of each Cleanroom. *See* Erickson Aff. at ¶ 2. Liberty did not design and install the HVAC systems that supplied air to and vented air from the Cleanroom. *See id.* at ¶¶ 2, 4. It also did not design or install the electrical or fire suppression systems. *See id.* at ¶ 2. Liberty did not provide the benches, hoods, or other equipment for the Cleanrooms to NECC. *See id.* at ¶ 3.

C. The 2006 Cleanroom Was Accepted by NECC, and Certified in Compliance with ISO 14644-1 After Construction in 2006, and Just Prior to the Outbreak in 2012.

The 2006 Cleanroom was completed and accepted by NECC in August, 2006. *See* Aug. 11, 2006 Job Completion Sign-Off Sheet and related correspondence, attached to the Erickson Aff. as **Exhibit 3**. The 2006 Cleanroom was certified as compliant with ISO 14644-1 on July 12, 2006. *See* Jul. 12, 2006 Cleanroom Certification Report, a true and correct copy of which is attached to the Erickson Aff. as **Exhibit 4**.³ The 2005 and 2008 Cleanrooms were also certified in compliance with ISO 14644-1 after construction. *See* Oct. 7, 2005 Cleanroom Certification

³ Liberty arranged for the 2006 Cleanroom to be certified at NECC's direction. *See* Jul. 10, 2006 e-mail correspondence, attached as **Exhibit 5**. Liberty was concerned the certification testing may have been premature because, among other reasons, the HVAC system had not yet been balanced, and the room and doorways thereto were not yet completely sealed. *See id.* NECC instructed Liberty to proceed regardless and in fact, the 2006 Cleanroom surpassed expectations and was certified by the third-party company that performs such services. *See e.g.* Exhibit 4 and Erickson Aff. at ¶ 11, n. 1, and n. 2.

Report, attached to the Erickson Aff. as **Exhibit 6**, and Mar. 6, 2008 Cleanroom Certification Report, attached as **Exhibit 7** to the Erickson Aff.

NECC hired Scientific Air Analysis, Inc. (“SAA”) to test and certify the functioning of the 2006 Cleanroom and its equipment at least bi-annually. *See* Erickson Aff. at ¶¶ 24, 29. The last test performed by SAA was completed on June 22, 2012 and was effective through December 31, 2012. *See* SAA invoice and Cleanroom Certification Report, attached hereto as **Exhibit B**. The SAA report demonstrates that the 2006 Cleanroom was functioning as required of a Class 6 cleanroom in compliance with ISO 14644-1 as late as June 22, 2012. *See id.*

D. NECC Did Not Follow Proper Cleanroom Protocols, and Compounded and Distributed Contaminated Preparations.

NECC produced three contaminated batches of MPA. *See* Master Complaint at Exhibits 1 – 5. The contaminated batches were identified as Lot Nos. 05212012@68, 06292012@26, and 08102012@51. *See* Health Alert Network CDC Health Update, Dec. 20, 2012, at p. 5, attached as **Exhibit C** (from <http://emergency.cdc.gov/HAN/han00338.asp> (last accessed Aug. 28, 2012)); *see also* Master Complaint at Exhibit 1, p. 5. [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] NECC voluntarily recalled the contaminated MPA on September 26, 2012. *See* Urgent Voluntary Product Recall, attached hereto as **Exhibit E**.

NECC obtained the ingredients for MPA, compounded the MPA, filled vials with MPA, and shipped the vials to medical providers. *See e.g.* Invoice to NECC, Jul. 24, 2012, attached hereto as **Exhibit F**, and CDC Multistate Outbreak of Fungal Meningitis and Other Infections – Healthcare Facilities, attached hereto as **Exhibit G**, accessed from <http://www.cdc.gov/hai/outbreaks/meningitis-facilities-map.html>. The “predominant fungus” in

the recalled lots was *Exserohilum rostratum*, which is a fungus common in the environment. *See* CDC Multistate Outbreak of Fungal Meningitis and Other Infections, attached hereto as **Exhibit H**, accessed from <http://www.cdc.gov/hai/outbreaks/meningitis.html>. The outbreak was investigated by the Massachusetts Department of Public Health, Board of Registration in Pharmacy, and Food and Drug Administration in September and October, 2012 and their reports document the condition of the Facility at that time. *See* Master Complaint at Exhibits 1 – 5.

These state and federal officials found, among other conditions:

- failure to follow proper autoclaving techniques (Master Complaint at Exhibit 1);
- failure to clean powder hoods (Master Complaint at Exhibit 1);
- use of non-sterile ingredients in allegedly sterile preparations (Master Complaint at Exhibit 2);
- failure to take action when the environmental monitoring system indicated the presence of bacteria and mold in Cleanrooms (Master Complaint at Exhibit 2);
- shutting down the HVAC system every night (Master Complaint at Exhibit 2);
- failure to test compounded preparations after dilution (Master Complaint at Exhibit 3);
- failure to review unexplained discrepancies between batch specifications and results, failure to investigate sterility failures (Master Complaint at Exhibit 3);
- failure to adequately validate sterilization process (Master Complaint at Exhibit 4);
- procedures designed to prevent contamination during sterile preparations were not established, written or followed (Master Complaint at Exhibit 4);
- environmental monitoring was not performed in connection with daily operations (Master Complaint at Exhibit 4); and
- equipment and utensils were not cleaned, maintained, and sanitized as needed to prevent contamination (Master Complaint at Exhibit 5).

None of the failings cited by any state or federal agency identified any condition that can be attributed to Liberty. For example, the FDA found the Facility was not properly maintained, and in fact had a leaky roof dating back to June, 2012. *See* Master Complaint at Exhibits 4 and 5. Liberty was not responsible for the condition of the building as a whole, or NECC's (or its landlord's) failure to maintain the building. *See* Erickson Aff. at ¶ 17. Liberty also never contracted to perform any work to the roof. *See id.* at ¶¶ 15-17.

In fact, Liberty did not contract with NECC to provide any maintenance, cleaning, or contamination control services to NECC. *See id.* at ¶ 17. Liberty offered training in the proper operation of the Cleanrooms, without charge, to NECC (as Liberty does for all of its customers), but NECC did not accept the offer for training. *See id.* at ¶ 5. It similarly did not have any ongoing contractual obligations to determine or monitor whether NECC performed any cleanroom maintenance, cleaning, or contamination control. *See id.* at ¶ 17. Generally, a customer such as NECC that purchases a cleanroom develops its own standard operating procedures for cleanroom maintenance, cleaning, and contamination control. *See id.* NECC did in fact have its own standard operating procedures, and was responsible for cleaning its cleanrooms and practicing safe compounding techniques, including by disinfecting surfaces, following proper gowning protocols, and using sterile equipment and ingredients. *See, e.g.,* Excerpts of NECC's Standard Operating Procedures for NECC, excerpts of which are attached hereto as **Exhibit I**. However, Liberty did not contract with NECC to monitor whether NECC complied with its own policies regarding such practices. *See* Erickson Aff. at ¶ 17.

Three batches of MPA compounded by NECC were contaminated and linked to the fungal meningitis outbreak. *See* Exhibit C. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

E. NECC Also Made Significant Modifications to the Facility Some Time After NECC Accepted the Cleanrooms.

All of the the conditions cited in the Exhibits to the Master Complaint are alleged to reflect the condition of the Facility at the time of the outbreak in September and October, 2012, not the condition when Liberty completed construction of the 2006 Cleanroom (or when it completed the 2008 Cleanroom for that matter). *See* Master Complaint at Exhibits 1 – 5. The Facility was in a much different condition in July, 2014 when Liberty participated in a site visit of the Facility. *See* Erickson Aff. at ¶¶ 21-22. Air return grilles were blocked, door sweeps were removed, leaving gaps in their place, none of the later-performed wall or ceiling penetrations (such as plumbing, electrical, surveillance or fire suppression systems) were caulked and sealed, door gaskets were missing or damaged, all of the gaskets on Liberty's pass-thru units were damaged, roof holes allowed daylight to penetrate the building, and deceased insects and a dead bird were *inside* one of the Cleanrooms. *See id.* at ¶ 22.

Each of these modifications to the Cleanrooms adversely affected the functioning of the Cleanrooms by, among other effects, preventing the HVAC from maintaining the required temperature and pressure (when it was actually on), and allowing contaminants to enter the Cleanroom environment. *See id.* at ¶ 23. The condition of the Facility upon inspection in 2014 (consistent with its condition in October 2012 as described in government reports) further demonstrated that NECC did not properly maintain its Cleanrooms. *See id.*

It was also seen that the machine used for filling vials with compounded preparations was located adjacent to an inoperable door, and in a lower-class room than that required by the

relevant regulations, further demonstrating that personnel performed what should have been aseptic processing in a non-sterile environment. *See id.* at ¶ 22.

IV. Plaintiffs’ Negligence Claims Fail as a Matter of Law

A. Liberty Did Not Breach any Duty to Plaintiffs.

Plaintiffs’ negligence claims fail as a matter of law. The undisputed material facts demonstrate that Liberty delivered fully functioning and regulation-compliant cleanrooms to NECC. There is no evidence of any breach of duty by Liberty. Indiana requires a plaintiff to prove three elements for a negligence claim: 1) defendant owed a duty to the plaintiff; 2) defendant breached its duty to plaintiff; and 3) plaintiff sustained injuries proximately caused by defendant’s breach. *See Kincade v. MAC Corp.*, 773 N.E. 2d 909, 911 (Ind. Ct. App. 2002) (affirming summary judgment for defendant because there was no evidence that defendant proximately caused plaintiff’s injuries). Every element of a negligence claim must be supported by specific facts, or reasonable inferences drawn from specific facts, but “an inference is not reasonable when it rests on no more than speculation or conjecture.” *Id.* at 911. A defendant may defeat a negligence claim on summary judgment if it demonstrates that the undisputed facts “negate at least one element of the plaintiff’s claims.” *Id.* (internal citations omitted).

The element of breach may be decided as an issue of law on summary judgment when there is no evidence that the alleged breach occurred. *See Green v. Whiteco Indus., Inc.*, 17 F.3d 199, 202 (7th Cir. 1994) (affirming summary judgment where plaintiff failed to offer any evidence of a malfunction to support an alleged breach of duty). In *Green*, the plaintiff, a musician, alleged that the defendant, a sound engineer, negligently operated a sound system during a concert and caused a sudden “sound blast” that knocked plaintiff off his seat and caused permanent hearing loss during a concert. *See id.* at 200-201. No evidence was provided by

plaintiff that the sound system malfunctioned or was not operated properly by the engineer. *See id.* at 202. Because there was no evidence of any defect in the system or the engineer's operation of it, there was no evidence of a breach of duty and summary judgment was affirmed. *See id.*

Plaintiffs cannot prove that Liberty breached a duty (even assuming a duty was owed to Plaintiffs) because the undisputed material facts demonstrate that Liberty provided fully-functioning and regulation-compliant cleanrooms to NECC. Plaintiffs allege Liberty owed a duty to Plaintiffs to "manufacture, construct, install, and/or design the NECC/Ameridose Cleanrooms in such a manner as to prevent the contamination of pharmaceuticals compounded within them." *See* Master Complaint, ¶ 128. Plaintiffs further allege that Liberty owed a duty to Plaintiffs to follow all applicable laws in cleanroom construction, design, certification, and ongoing maintenance. *See id.* at ¶ 212. This is precisely what Liberty did. Plaintiffs cannot put forward any evidence to support their claims that Liberty breached any such duty.

Liberty provided three cleanrooms to NECC. Each cleanroom was certified as conforming to the air classification requirements of ISO 14644-1. Although Plaintiffs have not, and likely cannot, identify the cleanroom in which the contaminated MPA was compounded, there have been indications that it may have been compounded in the 2006 Cleanroom.⁴ The 2006 Cleanroom was certified as fully functioning in 2006, and was re-tested every six months. Indeed, the 2006 Cleanroom "passed" the certification test that was performed as recently as June 2012 and did not require re-testing until December 2012. *See* Exhibit B. Such indisputable evidence demonstrates that the 2006 Cleanroom was functioning as required. The state and

⁴ The documents produced to date by NECC do not aid in this inquiry. It is likely only through the deposition of Barry Cadden, the CEO and a pharmacist at NECC, and/or the depositions of other former NECC pharmacists, that the cleanroom in which the MPA was compounded may be identified. However, given the efforts of the Trustee and counsel for the Official Creditors' Committee in seeking stays of discovery of these individuals, and recent criminal charges, it is not clear whether such depositions may ever be taken. It would be disingenuous for Plaintiffs to argue this motion cannot be decided without taking such a deposition, when Plaintiffs have not taken any steps to secure their right to take such a deposition, *i.e.* by opposing the Trustee's Motion to Stay. *See* Dkt. No. 1342.

federal government reports of conditions of the Cleanrooms in 2012 are not evidence of the conditions in 2006. There is no evidence that the conditions noted in the investigative reports were caused by some act or failure to act by Liberty (*see infra* for further discussion of Plaintiffs' proof problems on the element of causation). Liberty performed in the manner contracted and in full compliance with the relevant regulations, and therefore did not breach any duty that could be owed to Plaintiffs. Liberty did not breach any obligation to warn of the potential of contamination from failure to properly sterilize equipment and drug ingredients, or from a failure to follow proper compounding practices. NECC had its own standard operating procedures and knowledge of cleanroom protocols thereby negating any potential duty owed by Liberty. Because a breach of duty is an essential element for which Plaintiffs have the burden of proof and Plaintiffs cannot meet their burden, judgment must enter for Liberty on the negligence claims (Count I).

B. Liberty Did Not Proximately Cause Plaintiffs' Injuries.

When the undisputed facts “negate at least one element of the plaintiff’s claim,” negligence claims may be decided on summary judgment. *Vandenbosch v. Daily*, 785 N.E.2d 666, 668 (Ind. Ct. App. 2003) (affirming summary judgment for defendant based on lack of proximate cause). An injury is proximately caused by an act “if it is the natural and probable consequence of the act and should have been reasonably foreseen and anticipated in light of the circumstances...[it] requires, at a minimum, that the harm would not have occurred but for the defendant’s conduct.” *Id.* at 671 (internal citations omitted). There still must be specific facts, and not merely “supposition or speculation” regarding causation offered by a plaintiff to survive summary judgment. *See id.* A determination of proximate cause will become a question of law when only a single conclusion can be drawn from the facts. *See id.* at 671.

In *Vandenbosch*, the plaintiff exited a house head-first through a second-story window during a house fire. *See id.* at 666-667. The Court found that the landlord had a duty to provide a portable fire escape ladder in a safe and operating condition to the plaintiff. The landlord had provided a ladder, but the plaintiff never attempted to use it. *See id.* at 671. Because the plaintiff did not attempt to use the ladder, even had the landlord failed to provide a safe ladder, the Court concluded that any breach could not proximately cause plaintiff's injuries. *See id.* at 671-672.

Here, even if there were evidence of breach (which there is not), any alleged breach by Liberty was not a proximate cause of Plaintiffs' alleged injuries.

1. There is No Evidence That Any Act by Liberty Caused Plaintiffs' Injuries.

There is no evidence that but for Liberty's actions, Plaintiffs would not have been harmed. The undisputed evidence demonstrates that Liberty provided to NECC three Cleanrooms that all complied with mandatory specifications on the "cleanliness" of each room. Liberty did not do, or fail to do, *anything* that caused Plaintiffs' harm.

Even if there were evidence – not merely "supposition or speculation" – that Liberty breached a duty, there is no evidence that Plaintiffs' injuries are the natural and probable consequence of Liberty's actions. If Liberty breached a duty and therefore provided a compromised cleanroom, then the natural, probable, and foreseeable result would be widespread contamination of all or substantially all drugs compounded in Liberty's cleanrooms. In other words, if there was a systemic failure by Liberty in constructing a cleanroom, then it is probable, and reasonably foreseeable, that more than three random batches of MPA would have been contaminated. Instead, there is evidence that non-contaminated MPA was compounded both *before and after* the batches of contaminated MPA. Furthermore, according to records produced to date, the Cleanrooms were tested every six months and the 2006 Cleanroom passed every test,

including as recently as June, 2012. *See* Exhibit B. This evidence leads to only one conclusion – that even if Liberty had breached a duty and there was some defect with the cleanrooms, Plaintiffs’ alleged injuries were not proximately caused by Liberty. Judgment for Liberty must enter.

2. There is Overwhelming Evidence that NECC’s Poor Practices Caused Plaintiffs’ Harm.

The evidence demonstrates unequivocally that NECC caused Plaintiffs’ harm. The strength of this evidence is overpowering such that Plaintiffs’ claims against Liberty fail as a matter of law. Even were Liberty negligent in constructing the Cleanrooms, a negligent defendant who “sets into motion a chain of events” will not be liable for an “ultimate injury [that] was not reasonably foreseeable as the natural and probable consequence of the act or omission.” *See Control Techniques, Inc. v. Johnson*, 762 N.E.2d 104, 108 (Ind. 2002) (finding no error for failing to give separate jury instruction on superseding causes because it was covered by the instruction on proximate cause). A “superseding cause” is an event that is “not reasonably foreseeable” and it means the “original actor did not cause the harm and receives zero share of any liability.” *Id.* at 109.

The investigations by the Massachusetts Department of Public Health, Board of Registration in Pharmacy, and Food and Drug Administration all document the systemic failures by NECC in monitoring its Facility for cleanliness and preventing contamination (in addition to its failure to comply with regulations requiring prescriptions for each compounded drug). These failures by NECC are the proximate cause of Plaintiffs’ injuries. NECC obtained the ingredients for MPA, compounded the MPA, filled vials with MPA, and shipped the vials to medical providers. NECC was responsible for cleaning its cleanrooms and practicing safe compounding techniques by disinfecting surfaces, following proper gowning protocols, and using sterile

equipment and ingredients. In light of the deplorable conditions in which the Facility and the Cleanrooms were maintained, it is in fact a natural and probable consequence, and reasonably foreseeable, that NECC's failure to follow proper compounding practices was the proximate cause of Plaintiffs' alleged injuries. However, NECC's wholesale failure to follow required practices were not foreseeable to Liberty such that Liberty did not cause Plaintiffs' harm and cannot be liable for it. *See id.* at 110. There being no genuine dispute as to any material fact to the contrary, summary judgment for Liberty is warranted.

3. NECC's Modifications to the Facility Are Another Superseding and Intervening Factor.

Liberty provided Cleanrooms that were compliant with ISO 14644-1 at the time of construction and during subsequent inspections. In addition to NECC's other failures, the Cleanrooms were substantially altered since Liberty was last at the Facility in 2008. This was another superseding event which Liberty could not predict and for which Liberty cannot share any liability. *See Control Techniques, Inc.*, 762 N.E.2d at 109.

The modifications made to the Cleanrooms adversely affected the functioning of the Cleanroom as a "clean" and controlled environment. The removal of sealants around doors, coupled with the addition of unsealed wall and ceiling penetrations, the presence of rust and mold on equipment and fixtures, and the interruptions to the HVAC system from turning it off at night, all would have increased the number of particles that could enter the Cleanroom, and caused pressure fluctuations that would have inhibited the ability of the room to function at a Class 6 level. Liberty had no control, and indeed no knowledge of, any of the subsequent modifications to or operation of the Cleanrooms after they were constructed. Liberty did not proximately cause Plaintiffs' injuries because NECC made substantial changes to the Facility after Liberty left the jobsite. The documented condition of the Facility upon inspections in

October and December, 2012 demonstrated that NECC did not properly maintain its Cleanrooms and in fact had substantially altered the Cleanrooms since Liberty was last at the Facility. Such changes are superseding and intervening causes that completely break any potential chain of liability between Plaintiffs and Liberty. *See Control Techniques, Inc.*, 762 N.E.2d at 109.

Because there is no evidence that Liberty did not properly construct the Cleanrooms, and there is overwhelming evidence that NECC modified the Cleanrooms in material ways that altered their functioning, as well as evidence that NECC recklessly compounded drugs at its Facility, Plaintiffs cannot prove that *Liberty* caused Plaintiff's harm and judgment must enter for Liberty as a matter of law.

V. Plaintiffs' Claims for Gross Negligence Fails as a Matter of Law

Plaintiffs' complaints adopt or mimic the allegations of the Master Complaint, which does not include a separate count for gross negligence; instead the claim is subsumed within the negligence count. *See* Master Complaint at ¶¶ 211 – 217. Gross negligence is generally defined as “[a] conscious, voluntary act or omission in reckless disregard of ... the consequences to another party.” *N. Indiana Pub. Serv. Co. v. Sharp*, 790 N.E.2d 462, 465 (Ind. 2003) citing Black's Law Dictionary 1057 (7th ed. 1999). Plaintiffs must put forward specific evidence to show that Liberty breached its duty to provide a Cleanroom that would not contaminate drugs compounded by NECC by engaging in a conscious, voluntary act in reckless disregard of the consequences to Plaintiffs. *See id.* Plaintiffs cannot prove that any act or failure to act by Liberty was grossly negligent for the same reasons that the negligence claim fails. *See supra.* Any claim of gross negligence also fails because any act or failure to act by Liberty does not rise to the level of gross negligence. Judgment must enter for Liberty on this claim.

VI. There is No Basis for an Award of Punitive Damages

The claim for punitive damages (Count XIV) contained in the Master Complaint and incorporated into Plaintiffs' complaints also fails as a matter of law because Liberty did not engage in any behavior warranting punitive damages. Such damages are "not commonplace and rarely appropriate." *Yost v. Wabash College*, 3 N.E.3d 509, 524 (Ind. 2014). In order to recover punitive damages, Plaintiffs have a burden of proof – by clear and convincing evidence – that Liberty engaged in "'willful and wanton misconduct' such that 'the defendant subjected other persons to probable injury, with an awareness of such impending danger and with heedless indifference of the consequences.'" *Id.* at 523. (internal citations omitted). In the alternative, Plaintiffs could prove (still by clear and convincing evidence) "conduct constituting malice, fraud, gross negligence or oppressiveness [that was] accompanied by further evidence 'inconsistent with the hypothesis that the tortious conduct was the result of mistake of law or fact, honest error of judgment, overzealousness, mere negligence, or other noniniquitous human failing.'" *Bud Wolf Chevrolet, Inc. v. Robertson*, 519 N.E.2d 135, 137 (Ind. 1988) (internal citations omitted) (affirming award of punitive damages and reciting standard applicable in both tort and contract actions). There is simply no evidence to support a claim for punitive damages.

Plaintiffs' claims for "wrongful death punitive damages" (Count XII) also fail for these same reasons.⁵ However, they also fail because Indiana law does not permit a plaintiff to recover punitive damages in an action against another for wrongful death. *See* IND. CODE. § 34-23-1-2(c)(2)(B)(1999) (recoverable damages may not include punitive damages); *see also Durham ex. rel. Estate of Wade v. U-Haul Intern.*, 745 N.E.2d 755, 763 (Ind. 2001).

Judgment must enter for Liberty on the punitive damages claims as well.

⁵ *See* Appendix I for identification of those six cases which include this additional claim.

VII. The Loss of Consortium Claims Fail With the Negligence Claims

Many Plaintiffs are spouses with a loss of consortium claim.⁶ These claims are “derivative of the injured spouse’s personal injury claim.” *Estate of Wade*, 745 N.E.2d at 764. They depend on survival of the underlying action for personal injury, and if that claim fails, so too does the loss of consortium claim. *See id.* Plaintiffs’ contingent claims cannot survive summary judgment because the underlying negligence actions are without support in fact and law. There is no genuine issue of material fact, and Plaintiffs cannot prove that Liberty caused any Plaintiffs’ injuries. Therefore, the negligence claims fail, negating the ability of any loss of consortium claims to survive. Judgment must enter for Liberty on these claims.

CONCLUSION

Liberty is entitled to judgment as a matter of law on all of Plaintiffs’ claims. Liberty did not breach any duty to Plaintiffs to stop NECC from contaminating the MPA it compounded. Liberty did not cause Plaintiffs’ injuries. Liberty did not cause or contribute to the events leading up to the fungal meningitis outbreak. Liberty did not engage in any act, nor fail to act, in any manner that constitutes gross negligence or warrants punitive damages. Punitive damages are also not recoverable in actions based on wrongful death, and any loss of consortium claim fails because it is derivative of an action for personal injury to a spouse, and all such underlying claims fail as a matter of law.

WHEREFORE, Defendant Liberty Industries, Inc. respectfully requests this Court ORDER judgment for Liberty on all of Plaintiffs’ claims.

⁶ See Appendix I for a listing of those cases which include a loss of consortium claim.

Respectfully submitted,

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By its attorneys,

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Dated: October 6, 2014

CERTIFICATE OF SERVICE

Pursuant to Local Rules 5.2(b)(2) and 5.4, and 56.1 of the Local Rules of the United States District Court for the District of Massachusetts, I hereby certify that this document, filed through the ECF system, will be sent electronically in redacted form to the registered participants as identified on the Notice of Electronic Filing and that paper copies will be sent by first-class mail to those indicated as non-registered participants, if any, on October 6, 2014. An unredacted copy, with all accompanying unredacted exhibits, will also be delivered by first-class mail to counsel for Indiana Plaintiffs and the Plaintiffs' Steering Committee, and by hand to the United States District Court for the District of Massachusetts and the chambers of The Honorable Rya W. Zobel.

/s/ Peter G. Hermes

Peter G. Hermes